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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/245,625	02/05/1999	ROBERT R. BURCH	BUR-020	5098
31344	7590	04/13/2005	EXAMINER	
RATNERPRESTIA			BERKO, RETFORD O	
P.O. BOX 1596			ART UNIT	
WILMINGTON, DE 19899			PAPER NUMBER	
			1618	

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/245,625

Applicant(s)

BURCH ET AL.

Examiner

Retford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 14, 19 and 30-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 14, 19 and 30-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgement: Applicant's amendment and 37 CFR Sec 132 Declaration filed 12/10/04 is acknowledged.

Status of Claims

1. The status of the claims is as follows:

Claims 1, 10, 14, 19 and 30-45 are pending in the application.

2. **Withdrawal of Claim Rejections:**

The rejection of claims 1, 10, 14 and 19 under 35 USC -Sec 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contained subject matter which was not described in the specification is withdrawn in view of applicant's remarks.

Claim Rejections-35 USC Sec. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 10, 14, 19, and 30-45 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Burch et al (US 5, 433, 226) in view of Hill (US 5, 098, 711) further in view of Erikson et al (US 5, 499, 917).

The claims are directed toward a fiber comprising an elastomeric polymer capable of imbibing a chemotherapeutic agent (therapeutically effective amount) wherein the fiber has a core of a segmented polymer. The claims are also directed toward the segmented polymer having soft segment (polyester, polyether or mixture) and a hard segment (urethane); wherein the soft and hard segments are held together by covalent bonds and wherein the fiber has imbed or dispersed therein chemotherapeutic agents (e.g. a fluoride salt of known ppm) and said fiber having specified physical characteristics such as denier value, tensile strength and break elongation values. The claims are further directed toward a method for preparing a fluoride containing fiber, assembling such fiber into a dispensing box or kit containing dental floss made of comprising said fibers, wherein the fibers are continuous strands.

Burch et al (Patent '226) disclose the limitations in instant claim 1. Patent '226 discloses dental floss fiber having a core of segmented polymer wherein the polymer has soft segments and hard segment joined by covalent bonds (abstract, col 3, lin 35-50; col 5, lin 35-60 and Patent claims 1, and 8-9 at col 11, lin 20-25). As in applicant's claim 1, the soft segment is made of polyether and polyester and the hard segment is made of urethane (Patent claim 23 at col 12, lin 60-65). As in applicant's claim 1, Patent '226 discloses the physical characteristics—e.g. denier,, tensile strength and break elongation values (Patent claims 22 at col 12, lin 50). According to applicant's examples in the specification (page 4, lin 30 and pages 13-17) spandex or Lycra are

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polymers used for making dental floss fibers---as Patent '226 discloses the use of these polymers in the invention, Patent '226 disclose the physical characteristics of the fibers as in the instant claims (col 7, lin 15-65 and col 6, lin 5-25) and also discloses dental floss kit or box for dispensing the dental devices (col 9, lin 25 and col 10, lin 10-20).

Patent '226 does not disclose the use of a drug, medicament or therapeutic agent in the polymer or fibers.

Hill et al (Patent '711) discloses a method of treating dental cavities, gingivitis and periodontitis (abstract, Patent claim 11 at col 40, lin 30-50, continuing to Patent claims 12 and 13 at col 41 and col 42) with chemotherapeutic agents released from multi-strand dental floss comprising filaments (col 12, lin 10-20). More significantly, according to Hill et al, antibiotics, chemicals such as stannous fluoride, anti-plaque or anti-gingivitis agents, buffering agents and other ingredients can be introduced (col, 15, lin15) added (col 15, lin 36 and col 18, lin 36) or loaded (col 19, lin 13-30 and col 20, lin 30-40). Giving broad interpretation to applicant's claims, examiner takes the position that the language used in Patent '711 wherein chemicals and ingredients are introduced or added or loaded into the fibers is for all intent and purposes is deemed to be equivalent to the language in applicant's claim 1 wherein the fibers are capable of "imbing" chemotherapeutic agents.

Erikson et al (Patent '917) disclose an invention wherein elastic fibers are arranged as a dental device (dental dam), said dental fibers are of type called Lycra XA 700 or spandex fibers (col 3, lin 45-65; col 7, lin 50-55 and col 8, lin 10-15). Most significantly, Patent '917 specifically discloses that medicaments e.g. bactericidal agents and/or fungicidal agents and

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other agents that will be apparent to those skilled in the art may be added to the fibers as desired (col 4, lin 31-37).

One of ordinary skill in the art would have been motivated to make a floss or dam comprising Spandex or Lycra fibers as dental floss devices and add, introduce or load into said fibers chemotherapeutic agents such as antibacterial, anti-gingivitis and anti caries agents (e.g. stannous fluoride or sodium fluoride). One of ordinary skill would expect to obtain reasonable success in obtaining a dental floss that would be as easy to use and enhance patient comfort during usage as was achieved in Patent '971 (col 7, lin 20-40). More importantly, the motivation to combine the prior art references cited lies in the fact that one of ordinary skill would be undoubted to find it useful or desirable and indeed beneficial to add chemotherapeutic agents to the dental fibers in order to control dental infection and dental diseases through application of said dental floss made of fibers having known dental prophylactic or chemical agents impregnated therein as this was suggested by Erikson et al (Patent '917, col 4, lin 31-37). Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

1. Claims 1, 10, 14, 19, and 30-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burch et al (US 5, 433, 226) in view of Hill (US 5, 098, 711) further in view of Jacobson et al (US 5, 595, 750).

The disclosures of Burch et al (Patent '226) are discussed.

Patent '226 does not disclose the use of a drug, medicament or therapeutic agent in the polymer or fibers.

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We have also discussed the disclosures in Hill et al (Patent 711) in meting the limitations not disclosed in Patent '226.

Jacobson et al (Patent '750) disclose the use spandex or elastomeric fibers or filaments wherein is incorporated antimicrobial agents (col 8, lin 25-65; continuing to col 9, lin 1-30 and col 19, lin 60-65). According to Jacobson, the fibers are useful for making dental devices (col 11, lin 15-20). More importantly, Jacobson et al further disclose the motivation for making dental devices comprising spandex fibers wherein is incorporated antimicrobial agents:---the use of chemical agents in the fibers for controlling a broad spectrum of gram-negative and gram- positive bacteria (col 10, lin 40-65).

One of ordinary skill in the art would have been motivated to make a floss or dam comprising Spandex or Lycra fibers as dental floss devices and add, introduce or load into said fibers chemotherapeutic agents such as antibacterial, anti-gingivitis and anti caries agents (e.g. stannous fluoride or sodium fluoride). One of ordinary skill would expect to obtain reasonable success in obtaining a dental floss that would be as easy to use and enhance patient comfort during usage as was achieved in Patent '971 (col 7, lin 20-40). More importantly, the motivation to combine the prior art references cited lies in the fact that one of ordinary skill would be undoubted to find it useful or desirable and indeed beneficial to add chemotherapeutic agents to the dental fibers in order to control dental infection and dental diseases through application of said dental floss made of fibers having known dental prophylactic or chemical agents impregnated therein as this was suggested by Jacobson et al (Patent '750, col 10, lin 40-60). Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

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Response To Arguments

Applicant's remarks and the 37 CFR Sec 132 Declaration have been fully considered but are found unpersuasive because:

- a. the 37 CFR Sec 132 Declaration provides theoretical basis and illustration of polymer fibers and is found not commensurate in scope with the claimed subject matter sufficient to overcome or rebut the evidence for obviousness of the instant invention as determined by the Board of Patent Appeals and Interferences (March 23, 2004 decision).
- b. examiner does not find theoretical basis and illustration of polymer fibers as provided in the Declaration as sufficient to establish the generic nature of the fibers and in addressing the scope of the claims.
- c. the issues raised by the present remarks by applicant are the same as those previously dealt with in the Board of Patent Appeals and Interferences decision referenced above.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

R+B

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application

Information Retrieval (PAIR) system. Status information for published applications may be

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


THURMAN K PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600